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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/477,962	01/05/2000	BEN SHEN	2500.125US2	9979
. 7:	590 12/04/2002			
	of Jonathan Alan Qui	EXAMINER		
P O Box 458 Alameda, CA 94501			KERR, KATHLEEN M	
			ART UNIT	PAPER NUMBER
			1652	10
			DATE MAILED: 12/04/2002	. ( )

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	09/477,962	SHEN ET AL.				
Office Action Summary	Examiner	Art Unit				
	Kathleen M Kerr	1652				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).  Status	36(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days fill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. 8 133)				
1)⊠ Responsive to communication(s) filed on 20 S	Responsive to communication(s) filed on <u>20 September 2002</u> .					
	s action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims	•					
4)⊠ Claim(s) <u>1-3,5,9,10,12-15,17,21,40-45 and 71-</u>		on.				
	4a) Of the above claim(s) is/are withdrawn from consideration.					
5)⊠ Claim(s) <u>9</u> is/are allowed.	Claim(s) <u>9</u> is/are allowed.					
6)⊠ Claim(s) <u>1-3,5,10,17,21,40-45 and 71-73</u> is/are	☑ Claim(s) <u>1-3,5,10,17,21,40-45 and 71-73</u> is/are rejected.					
7)⊠ Claim(s) <u>12-15</u> is/are objected to.	☑ Claim(s) <u>12-15</u> is/are objected to.					
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.						
12)☐ The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
<u> </u>	1. Certified copies of the priority documents have been received.					
	2. Certified copies of the priority documents have been received in Application No					
application from the International Bure	<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
<ul> <li>14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).</li> <li>a) ☐ The translation of the foreign language provisional application has been received.</li> </ul>						
15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachment(s)						
Notice of References Cited (PTO-892)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16	5) Notice of Informal P	(PTO-413) Paper No(s) atent Application (PTO-152)				

U.S. Patent and Trademark Office PTO-326 (Rev. 04-01)

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#### **DETAILED ACTION**

## **Application Status**

1. In response to the previous Office action, a non-Final rejection (Paper No. 13, mailed on March 12, 2002), Applicants filed an amendment and response received on September 20, 2002 (Paper No. 15). Said amendment cancelled Claims 4, 6-8, 11, 16, 18-20, 22-39, and 46-70 and amended Claims 1-3, 5, 9, 10, 12-15, 17, 21, 40, 72, and 73. Thus, Claims 1-3, 5, 9, 12-15, 17, 21, 40-45, and 71-73 are pending in the instant Office action and will be examined herein.

#### **Priority**

- 2. As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application No. 60/115,435 filed on January 6, 1999 and 60/118,848 filed on February 5, 1999 as requested in the declaration and the first lines of the specification.
- U.S. Provisional application 60/115,435 does not contain any sequence information. U.S. Provisional application 60/118,848 does contain sequence information relative to SEQ ID NO:115 (the polypeptide) and SEQ ID NO:1 (57583-58854bp) (the encoding nucleotide sequence). Applicants have adequately explained the typographical error in U.S. Provisional application 60/118,848 such that it is apparent that Applicants were in possession of the claimed invention at the time of filing said provisional application. Thus, Claims 1-3, 5, 9, 12-15, 17, and 40-45 are granted an earliest effective filing date of February 5, 1999 while Claims 21 and 71-73 are granted an earliest effective filing date of January 6, 1999 since no SEQ ID NOs are referred to in said claims.

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## Information Disclosure Statement

3. The information disclosure statement filed on September 20, 2002 (Paper No. 16) has been reviewed, and its reference has been considered as shown by the Examiner's initials next to each citation on the attached copy. A copy had been previously filed with the Office in association with the instant application.

#### **Drawings**

4. The drawings filed on September 20, 2002 are considered informal for the reasons detailed in the attached copy of PTO Form 948. Appropriate correction is required in response to the instant Office action and may not be held in abeyance (see 37 C.F.R. § 1.85(a)).

## Sequence Rules Compliance

- 5. Due to the amendment to the specification concerning Figure 8C, the instant application is in full compliance with the sequence rules.
- 6. As previously noted, the sequence listing, specifically related to the DNA of the gene cluster, is confusing because the references to various accession numbers and the division of the entire gene cluster between SEQ ID NOs: 1 and 2. Moreover, the positions of ORFs noted in the specification are unclear due to this division. Clarification of the definition of the gene cluster sequence in the sequence listing is required.

Applicants argue that the sequence listing need not be redone; however, the Examiner did not request such an arduous process. If the specification were amended to clearly set forth how SEQ ID NOs: 1 and 2, together, make up the complete set of orf genes as depicted in Table II, the instant objection would be obviated.

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From the Examiner's search, it is clear that orf8 (polypeptide sequence SEQ ID NO:115) "position 76183-77457" in Table II is base pairs 57583-58832 of SEQ ID NO:1 (the end of SEQ ID NO:1). It seems reasonable that orf9 (polypeptide sequence SEQ ID NO:114) immediately precedes orf8 (moving 3' to 5') on SEQ ID NO:1. Following this trend, orf30 (polypeptide sequence SEQ ID NO:93) is located at the beginning (5' end) of SEQ ID NO:1. At this point, the trend switches wherein orf31 is located at the beginning (5' end) of SEQ ID NO:2 and orf40 is located at the end (3' end). Thus, while the "position" numbers in Table II are linear, the sequence must be followed 3' to 5' on SEQ ID NO:1 then to 5' to 3' on SEQ ID NO:2. This interpretation is **wholly** confusing and arduous considering the disclosure in Table II. Applicants are required to amend Table II to include the positions relative to SEQ ID NOs of all the encoded orfs for clarity.

#### Withdrawn - Objections to the Specification

- 7. Previous objections to the specification for being confusing in the description of the drawings and/or throughout the specification have been withdrawn by virtue of Applicants' amendment concerning the following issues:
  - a) The description of Figure 9 mentions underlining while none is found in the figure.
  - b) In the description of Figure 11, Figures 11A-11D must be described separately.
  - c) On page 47, line 19, the reference to "(18)" is unclear.
  - d) On page 70, line 29, the reference to "(FIGURE)" is unclear.

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## Maintained - Objections to the Specification

8. Previous objection to the specification for being confusing in the description of the drawings and throughout the specification is maintained on particular points as follows.

Applicants' amendments and/or arguments were insufficient to obviate the objections:

- a) In the description of Figure 6, Figures 6A-6F must be described separately. A description of Figure 6F was omitted in the amendment.
- b) On page 19, line 14, the amendment of the accession numbers is acceptable; however, it is still unclear why two SEQ ID NOs are used to describe three accession numbers, particularly if, as noted by Applicants, AF210311 pertains to ptpA which is described in the instant specification as SEQ ID NO:3.
- c) In Table I on page 19, SEQ ID NOs of the amino acid sequences **would be** helpful. Applicants note that such an insertion would be confusing. The Examiner disagrees; SEQ ID NOs would only help to clarify the on-going problem between the confusing sequence listing and the specification as noted above.
- d) Also in Table I, the accession number "AA07904.1" is unclear and cannot be identified in GenBank. Applicants have deleted the accession number leaving behind an unclear, undefined term "RfaE". Clarification of this term is required.
- e) In Table II, the "position" reference is unclear since the gene cluster is apparently divided between SEQ ID NOs: 1 and 2. As noted above in the Sequence Compliance section, these position references are wholly unclear and must be clarified with respect to the sequence listing. Applicants argue that these position numbers are clear with respect to Figures 1B and 2. The Examiner disagrees. Figure 1B contains no reference to base pairs whatsoever and Figure 2 only contains reference to base pairs at the thousand base pair level.
- f) On page 69, the following accession numbers are unclear: "AL008967", "AL031107", and "AL049863". These numbers cannot be found in GenBank under **protein** databases as described on page 69; these numbers, as argued by Applicants, are found in the nucleotide database. Appropriate clarification is required.

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### Withdrawn - Claim Objections

9. Previous objection to Claims 1-20, 23, 65-66, and 68-69 for containing non-elected subject matter, particularly as follows, is withdrawn by virtue of Applicants' amendment:

- a) Claims 1-5 (independent Claim 1) have been amended (or cancelled) to be drawn to nucleic acid sequences encoding ORF 8 and optionally other orfs.
- b) Claims 6-8 have been cancelled.
- c) Claims 9-15 (independent Claim 9) have been amended (or cancelled) to be drawn to nucleic acid sequences encoding ORF 8 (SEQ ID NO:115) and optionally other orfs.
- d) Claims 16-18 have been cancelled.
- e) Claims 19-20 have been cancelled.
- f) Claim 23 has been cancelled.
- g) Claims 65-66 and 68-69 have been cancelled.
- 10. Previous objection to Claim 72 for containing a typographical error is withdrawn by virtue of Applicants' amendment.
- 11. Previous objection to Claim 42 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn by virtue of Applicants' amendment to Claim 40, from which Claim 42 depends.

#### Maintained - Claim Objections

- 12. Previous objection to Claims 21, 40-45, and 71-73 for containing non-elected subject matter, particularly as follows, is maintained:
  - a) Claim 21, as previously noted, contains *no specific reference* to ORF 8. Applicants argue that the invention claimed in Claim 21 "can comprise" elected ORF8; however, the

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election invention must be contained in the elected claims. While Claim 21 *can* comprise ORF8, it also cannot.

- b) Claims 40-45, as they depend from Claim 21, contain non-elected subject matter.
- c) Claims 71-73 contain *no specific reference* to ORF 8. Applicants argue that the invention claimed in Claim 21 "can comprise" elected ORF8; however, the election invention must be contained in the elected claims. This argument is valid for Claims 71-73. While Claims 71-73 can comprise ORF8, it also cannot.

Appropriate correction is required.

## Withdrawn - Claim Rejections - 35 U.S.C. § 112, second paragraph

- 13. Previous rejection of Claims 1-5, 9-20, 23, 40-45, 71-73 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "nucleic acid" is withdrawn by virtue of the Examiner's reconsideration.
- 14. Previous rejection of Claims 1-5 and 40-45 under 35 U.S.C. § 112, second paragraph, as being indefinite for the structure/indentations of Claim 1 is withdrawn by virtue of Applicants' amendment altering the structure so that it is now clear.
- 15. Previous objection to Claims 1-5 and 40-45 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "encoding" is withdrawn by virtue of Applicants' amendment.
- 16. Previous rejection of Claims 1-5, 10-20, and 40-45 under 35 U.S.C. § 112, second paragraph, as being indefinite for the reference ORF 8 is withdrawn by virtue of Applicants' amendment.

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- 17. Previous rejection of Claims 1-5 and 40-45 under 35 U.S.C. § 112, second paragraph, as being indefinite for being unclear as to how "the nucleic acid of a bleomycin-producing organism" can be used as a template is withdrawn by virtue of Applicants' amendment.
- 18. Previous rejection of Claims 2-5, 10-15, 20, and 40-45 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "said nucleic acid" with unclear antecedent basis is withdrawn by virtue of Applicants' amendment.
- 19. Previous rejection of Claims 9-15 and 40-45 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "a BLM gene cluster" is withdrawn by virtue of Applicant's amendment.
- 20. Previous rejection of Claims 9-15 and 40-45 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "a **BLM** gene cluster" is withdrawn by virtue of Applicant's amendment.
- 21. Previous rejection of Claims 16-18 and 40-45 under 35 U.S.C. § 112, second paragraph, as being indefinite for the optional domains in Claim 16 while the elected ORF 8 is only disclosed as containing an oxidase domain is withdrawn by virtue of Applicants' cancellation and/or amendment of said claims.
- 22. Previous rejection of Claims 16-18 and 40-45 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the metes and bounds of the nucleic acid sequence encoding

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the noted domains is withdrawn by virtue of Applicants' amendment and/or cancellation of said claims.

- 23. Previous rejection of Claims 16-18 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "stringent hybridization conditions" is withdrawn by virtue of Applicants' cancellation of said claim.
- 24. Previous rejection of Claim 73 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "a resistance gene from the bleomycin gene cluster" is withdrawn by virtue of Applicants' amendment.

# Maintained - Claim Rejections - 35 U.S.C. § 112, second paragraph

25. Previous rejection of Claims 40-45 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "stringent conditions" is maintained, and Claims 1-3 are added to the rejection by virtue of Applicants' amendment.

Claims 1-3 and 40-45 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In Claim 1, the term "stringent conditions" is unclear as to its metes and bounds. The definition found on page 10 described "preferential" hybridization to its target and "general" conditions for highly stringent, etc. These general conditions cannot be interpreted into the claims, nor can the definition for "highly stringent" be considered equivalent to "stringent".

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Page 10

Applicants argue that the definition on page 10 is adequate. However, the citation used in the argument described "highly stringent" conditions, which are not claimed.

26. Previous rejection of Claims 21 and 40-45 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "a bleomycin" of "a bleomycin analogue" is maintained.

Applicants' arguments have been fully considered but are not deemed persuasive.

Applicants do not argue concerning the term "a bleomycin" (emphasis added). The Examiner had questioned whether bleomycin is a single compound of a class of compounds. No answer was received to clarify this issue. Applicants argue that an "analogue" is clearly defined in the art by virtue of its recurrence in patent claims. Without a complete understanding of the claims and the specification, which can define the term, this argument is not persuasive. Is the analogue a structural analogue? a functional analogue? It is wholly unclear as to the metes and bounds of the structure.

- 27. Previous rejection of Claims 40-45 under 35 U.S.C. § 112, second paragraph, as being indefinite for the antecedent basis of "a nucleic acid" as it depends from parent claims. Claim 21, however, is not drawn to a nucleic acid as required for Claim 40. Appropriate correction is required.
- 28. Previous rejection of Claim 72 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "a resistance gene from the bleomycin gene cluster" is maintained.

  Applicants argue that the specification, on page 46, describes blmA and blmB as resistance genes

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of the bleomycin gene cluster rendering the term definite. However, by virtue of the amended dependent, further-limiting Claim 73, the term in Claim 72 has a broader scope whose definition is unclear.

# Withdrawn - Claim Rejections - 35 U.S.C. § 112, first paragraph

- 29. Previous rejection of Claims 1-5, 16-18, and 40-45 under 35 U.S.C. § 112, first paragraph, written description, for being drawn to nucleic acid sequences having limited structure and no function is withdrawn by virtue of Applicants' amendment. The amended function of having "oxidase activity" is sufficient to obviate the instant rejection as previously presented. However, since the structural limitations are unclear, as noted in the rejection under 35 U.S.C. § 112, second paragraph, above for "stringent conditions", the claims, as amended, as drawn to nucleotide sequences having a defined structure and no definite function, which type of rejection is maintained below.
- 30. Previous rejection of Claims 9-15 and 23 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicants' cancellation and/or amendment of said claims to be drawn to exact sequences.
- 31. Previous rejection of Claims 19 and 20 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicants' cancellation of said claims.

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32. Previous rejection of Claims 1-5, 9-20, and 40-45 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicants' amendment adding a required function into the claimed invention.

33. Previous rejection of Claims 21, 23, and 71-73 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicants' cancellation of said claims or by virtue of the Examiner's reconsideration.

## Maintained - Claim Rejections - 35 U.S.C. § 112, first paragraph

34. Previous rejection of Claims 21, 40-45, and 71-73 are rejected under 35 U.S.C. § 112, first paragraph, written description, is maintained as set forth below. Additionally, Claims 1-3 have been added since, by virtue of the lack of a clear limitation on structure, the subject matter has the same defect with respect to written description. The Examiner notes that if the rejection under 35 U.S.C. § 112, second paragraph is overcome for Claims 1-3, the written description rejection herein would also be obviated.

Applicants argue that Claims 21 and 71 have adequate description in the specification as originally filed because the specification "clearly allow[s] persons or ordinary skill in the art to recognize that [he or she] invented what is claimed". The Examiner disagrees that the specification provides enough description so that one of skill in the art could recognize what is being claimed. The specification provides a single example of the claimed invention. No characterization of the structure of the single example to the function of the broadly claimed genus is offered. Further, Applicants argue that Claims 21 and 71 do not recite particular functions. The Examiner wholly disagrees. As claimed, the gene cluster of Claim 21 must direct

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assembly of bleomycin, in other words, the gene cluster must function to encode proteins that catalytically biosynthesize bleomycin. This is clearly a function. Moreover, without a claimed function and without a claimed structure, the entire claim would be wholly unclear as to the product claimed.

Claims 1-3, 21, 40-45, and 71-73 are rejected under 35 U.S.C. § 112, first paragraph, written description, for the reasons previously cited and maintained above.

## Withdrawn - Claim Rejections - 35 U.S.C. § 102

- 35. Previous rejection of Claims 23, 40, 41, and 43-45 under 35 U.S.C. § 102(e) as being anticipated by Schupp *et al.* is withdrawn by virtue of Applicants' cancellation and/or amendment of said claims.
- 36. Previous rejection of Claims 16 and 17 are rejected under 35 U.S.C. § 102(b) as being anticipated by Redenbach *et al.* is withdrawn by virtue of Applicants' cancellation of said claims.

### Maintained - Claim Rejections - 35 U.S.C. § 102

37. Previous rejection of Claims 40, 41, and 43-45 under 35 U.S.C. § 102(b) as being anticipated by Redenbach *et al.* is maintained as set forth below. Additionally, Claim 1 has been added since, by virtue of the lack of a clear limitation on structure, the subject matter is anticipated by the art. Applicants' arguments have been fully considered but are not deemed persuasive.

Applicants argue that it has not been prima facie established that the Redenbach *et al*.

DNA encodes an oxidase as required by the added limitation of the claims. The Examiner

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disagrees. Redenbach et al. teach the nucleotide sequence as encoding an oxygen-independent

coproporphyrinogen III oxidase. Without having laboratory facilities to test the validity of such

claims, this assertion must be accepted on its face, just as the claims of the instant specification

define SEQ ID NO:115 as having oxygen-independent coproporphyrinogen III oxidase activity

without direct testing. Thus, the instant rejection is maintained.

Claims 1, 40, 41, and 43-45 are rejected under 35 U.S.C. § 102(b) as being anticipated by

Redenbach et al. for the reasons previously cited and maintained above.

**NEW ISSUES** 

Claim Objections

38. Claim 5 is objected to for having a period embedded within the text; this appears to be a

typographical error with the last half of the claim being a typographical error of inserted text.

39. Claims 12-15 are objected to for containing references to orfs using terms like "blmVIII"

instead of the SEQ ID NOs as used throughout the rest of the claims. Consistency in the claims

is required.

40. Claim 73 is objected to for having a typographical error. The comma after "blmA" is

inappropriate.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 41. Claims 5 and 10 and 40-45 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The language of Claims 5 and 10 is wholly unclear, seemingly due to typographical errors. If, in Claim 5, everything after the first period should be deleted, Claim 5 is equivalent to Claim 9. Similarly, Claim 10 could be considered identical to Claim 9. Clarification is required.
- 42. Claims 17 and 40-45 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The added limitation of encoding a module, when the parent claim is drawn to a specific polypeptide that is not part of the larger, polyketide synthase, modular make-up, is wholly unclear. Clarification is required.

#### Summary of Pending Issues

- 43. The following is a summary of the issues pending in the instant application. All must be addressed in a complete response to the instant Office action:
  - a) The specification stands objected to for being confusing in the description of the drawings and throughout the specification as noted above.
  - b) Claim 5 stands objected to for having a period embedded within the text.
  - c) Claims 12-15 stand objected to for containing inconsistent references to orfs using terms like "blmVIII".
  - d) Claims 21, 40-45 and 71-73 stand objected to for containing non-elected subject matter.

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- e) Claim 73 stands objected to for having a typographical error.
- f) Claims 1-3 and 40-45 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for 1, the term "stringent conditions".
- g) Claims 5, 10, and 40-45 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for being wholly unclear.
- h) Claims 17 and 40-45 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the added limitation of encoding a module.
- i) Claims 21 and 40-45 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "a bleomycin" of "a bleomycin analogue".
- j) Claims 40-45 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the antecedent basis of "a nucleic acid" as it depends from parent claim 21.
- k) Claim 72 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "a resistance gene from the bleomycin gene cluster".
- 1) Claims 1-3, 21, 40-45, and 71-73 stand rejected under 35 U.S.C. § 112, first paragraph, written description.
- m) Claims 1, 40, 41, and 43-45 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Redenbach *et al.*

#### Conclusion

44. Claim 9 is allowed; Claims 12-15 are objected to; Claims 1-3, 5, 10, 17, 21, 40-45, and 71-73 are rejected for the reasons identified in the numbered sections of this Office action.

Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

PONNATIVAPUACHUTAMURTHY SUPERVISORY PATERT EXAMINER TECHNOLITY OF THE 1000

KMK November 27, 2002